

Serial No. 10/633,772

Filed August 4, 2003

MS-02/3/US

Response to Office Action dated May 24, 2006

therewith. Applicant re-states for the record that authorization via Form PTO-2038 to charge \$65 for the terminal disclaimer filed on September 7, 2004 was given on March 18, 2005. That earlier terminal disclaimer was not recorded but the authorized payment was charged before Applicant was able to revoke the authorization. Thus Applicant has paid \$65 twice for the terminal disclaimer in the present application. Confirmation is respectfully requested in the next communication from the Office that Applicant presently stands \$65 in credit with respect to this application.

2. Allowable subject matter.

It is noted that Claims 24, 26–31 and 33–37 have been found allowable, subject to their rewriting in independent form including all of the limitations of the base claim and any intervening claims.

Applicant elects once again to defer amendment of these claims for allowance, pending reconsideration by the Examiner of the rejected base and intervening claims, in light of Applicant's submission herein.

3. Rejection under 35 U.S.C. §103(a) over Cohen in view of Sclan.

Claims 21–23, 25, 32 and 38 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cohen *et al.* (U.S. Patent No. 3,726,027) in view of Sclan & Reisberg (U.S. Patent No. 5,082,446). This rejection is respectfully traversed.

It is well established that a *prima facie* case of obviousness requires that all three of the criteria set forth in MPEP §2143 be met. A *prima facie* case of obviousness cannot be sustained in the present situation, for failure to satisfy at least two of the three criteria, as more fully described below.

3.1. No suggestion or motivation to combine reference teachings.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. MPEP §2143.01.

The present invention is defined as a “therapeutic method” wherein use of the recited kit

as a cognitive activity aid “provides a therapeutically beneficial cognitive challenge appropriate to the subject’s mental acuity” (Claim 21). Cohen provides an apparatus “for use in teaching children word associations and the like” (Cohen, column 1, lines 7–8). Applicant agrees with the Examiner’s finding that Cohen “does not disclose expressly a method involving an adult subject having a medically diagnosed dementia” (Office Action, page 4, lines 1–2). It is further noted that Cohen does not disclose a method providing therapeutic benefit to any subject. Nowhere does Cohen state, for example, that the subject apparatus is or can be used therapeutically, *i.e.*, in treatment of a disease or disorder such as cognitive impairment, illustratively providing specific therapeutic benefits as listed in the present specification (for example at page 5, line 16 – page 6, line 5).

Cohen’s apparatus is presented as a “teaching aid and educational toy” (Cohen, column 1, lines 19–20). One seeking to adapt Cohen’s apparatus, for the very different purpose of providing a therapeutically beneficial cognitive challenge appropriate to the mental acuity of an adult subject having a medically diagnosed dementia, would not, prior to the present invention, have been motivated to combine Cohen’s teaching with that of Sclan (even if such combination would somehow yield the method of the present invention, which, as shown below, is not the case). Lack of motivation is evidenced for at least the following reasons.

A. Sclan does not relate to a therapeutic method. Sclan provides a method for assessment of mental function in severely impaired dementia patients that is said to be analogous to measures (*i.e.*, test procedures) previously applied to infants and small children (Sclan, column 2, lines 26–30). Nowhere does Sclan state that the subject assessment method provides a therapeutic benefit to such patients. Disclosure by Sclan of a cognitive assessment method for dementia patients adapted from a cognitive assessment method used with infants would not lead one of ordinary skill in the art, seeking a therapeutic method for improving quality of life in an adult dementia patient, to adapt Cohen’s teaching aid and educational toy.

B. Sclan, read as a whole, teaches away from the combination. A prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. MPEP §2141.02. With the particular exception of Sclan’s claimed

assessment method, Sclan, when read as a whole, teaches that such methods are generally untranslatable from infants to dementia patients. For example, Sclan states that “[i]nfants are fundamentally different from patients with dementia” (Sclan, column 3, lines 4–5, emphasis added); that “[a]mong the differences are cognitive, motor and behavioral differences” (Sclan, column 3, lines 8–9); and that these differences “render the unmodified use of infant tests for dementia patients uninterpretable, misleading or, in some instances, impossible to administer” (Sclan, column 3, lines 21–24). Thus, a reading of Sclan as a whole would have led one of skill in the art to conclude that an apparatus useful as a teaching aid for infants (such as the apparatus of Cohen) would be unlikely to have benefit for an adult dementia sufferer. In other words, Sclan teaches away from the present combination of references.

Thus no suggestion or motivation can be found to combine the reference teachings.

3.2. All claim limitations not taught or suggested.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP §2143.03.

Among features recited in Claim 21 that are neither taught nor suggested by Cohen, Sclan or a combination thereof, are, most notably, a “therapeutic method” (preamble of Claim 21) that “provides a therapeutically beneficial cognitive challenge” (body of Claim 21, last two lines). Other features not taught or suggested by the presently cited art include (i) “a kit that comprises a plurality of pieces that have surface layers formed collectively of a plurality of soft fabrics that are distinguishable by touch and/or subsurface layers that are distinguishable by touch through a lightweight surface fabric,” and (ii) suitability of said pieces “for arrangement by the subject in a simple assembly or construction pastime, puzzle or game.”

3.2.1. Therapeutic method providing a therapeutically beneficial cognitive challenge.

The stated function of Cohen’s apparatus is, as indicated above, a “teaching aid and educational toy” (Cohen, column 1, lines 19–20). In the cognitive realm, teaching and education are directed to assisting natural development of cognitive abilities. By contrast, the method of the present invention as set forth in Claim 21 provides not an educationally beneficial, but a therapeutically beneficial, cognitive challenge. As clearly recognized by the present inventors,

an educational toy is not inherently therapeutic to adult dementia patients. “Simple children’s toys … are usually not well adapted to the particular needs of people whose mental and sensory faculties are in decline rather than in development” (Specification, page 1, lines 24–27).

The Examiner’s quotation from Cohen, column 4, lines 5–9 (Office Action, bottom of page 3) can be read as disclosure of a “cognitive challenge appropriate to the subject’s mental acuity” but, contrary to the Examiner’s assertion, not a therapeutically beneficial cognitive challenge. Nothing in the passage:

Thus, a child may be instructed to hold an outer face of a given color in a given position, and then to feel and describe the inner face corresponding to the selected color to form a word association between the color and the given texture.

suggests a therapeutic benefit of the described action, for example to an adult dementia patient.

Sclan’s method for assessing cognitive status of patients with severe dementia is likewise not a therapeutic method. Nowhere does Sclan hint at a therapeutic benefit to patients from practice of the method described therein. Even if motivation existed to combine Sclan with Cohen (which is not admitted herein), the resulting combination would offer no teaching or suggestion of a therapeutic method with therapeutic benefit as provided by the present invention.

3.2.2. Kit as defined in Claim 21.

Claim 21 defines a kit comprising a plurality of pieces. A kit is distinguished from an integral object in that it comprises separate pieces (Specification, page 2, lines 25–26). The pieces in Claim 21 “have surface layers formed collectively of a plurality of soft fabrics that are distinguishable by touch and/or subsurface layers that are distinguishable by touch through a lightweight surface fabric when handled by the subject.” The combination of Cohen and Sclan neither teaches nor suggests causing a subject to use a kit of separate pieces having touch-distinguishable surface and/or subsurface layers as a cognitive activity aid.

Cohen’s apparatus comprises a box, which can be “constructed from flat-form by students to instruct them how to read and follow directions” (Cohen, column 5, lines 1–3). However, as is clear from Fig. 1 of Cohen, even the “flat-form” apparatus is an integral object. Cohen does not contemplate providing separate square and triangular pieces to “students” to

have them tape these together to make the flat-form or box. A reading of Cohen as a whole makes it clear that Cohen's assembly instructions at column 2, lines 13–49 are directed to a person other than a "student", for example a teacher, who presents the flat-form or fully assembled box to the "student". Thus, even if the Cohen box has internal touch-distinguishable surfaces, as presented to the subject these are part of an integral article, not a kit of separate pieces. The Examiner's characterization of the Cohen box as a "kit" and the touch-distinguishable internal surfaces of the Cohen box as a "plurality of pieces" making up a kit (Office Action, page 3) ignores the definition of a "kit" provided in the present specification.

Cohen does provide a "plurality of illustration objects made of materials such as felt, paper or plastic" (column 4, lines 40–42) that can be attached by the subject to faces of the box (column 4, lines 60–67). The pieces recited in Claim 21 of the present application are distinct from the "illustration objects" of Cohen in having touch-distinguishable surface and/or subsurface layers.

3.2.3. *Pieces suitable for arrangement by the subject.*

The combination of Cohen and Sclan, even if motivation existed for such combination, neither teaches nor suggests pieces having touch-distinguishable surface and/or subsurface layers that are "suitable for arrangement by the subject" as required by Claim 21. As pointed out above, the touch-distinguishable layers of the Cohen apparatus as presented to the subject are affixed to the inner surfaces of the box and are not "suitable for arrangement by the subject". The Examiner's characterization of the internal surfaces of the Cohen box as being "suitable for arrangement by the subject" (Office Action, page 3) is therefore incorrect.

In summary, the reference teachings, even if motivation could be found to combine them, would not lead one of ordinary skill in the art to the present invention, as not all claim limitations are taught or suggested by a combination of the references.

3.3. *Dependent claims are not *prima facie* obvious.*

Each of Claims 22, 23, 25, 32 and 38 depends from Claim 21. As Claim 21 is believed to be non-obvious over Cohen in view of Sclan for reasons set forth above, all claims dependent therefrom are likewise non-obvious over the cited references. If an independent claim is non-

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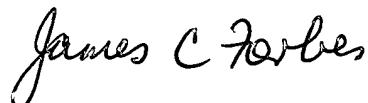
obvious under 35 U.S.C. §103, then any claim depending therefrom is non-obvious. MPEP §2143.03.

Further, with respect to Claims 22, 23, 25, 32 and 38, the Examiner's characterization of Cohen's "pieces", for example engaged to each other with adhesive tape, having opposing layers formed of soft fabrics having differing tactility, or having surface layers formed collectively of a plurality of soft fabrics (Office Action, pages 4–5), is incorrect, in that the so-called "pieces" attributed by the Examiner to Cohen are not separate pieces of a kit, as pointed out above.

For at least the reasons set forth above, Applicant respectfully submits that a *prima facie* case of obviousness has not been made, and requests withdrawal of the present rejection under 35 U.S.C. §103(a).

In view of (a) the above showing that a *prima facie* case of obviousness of Claims 21–23, 25, 32 and 38 has not been made and (b) allowability of the subject matter of 24, 26–31 and 33–37, Applicant believes the present application is in condition for allowance of all pending claims.

Respectfully submitted,



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